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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/703, 753 11/01/00 DUDLEY

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EXAMINER

JIANG, S

ART UNIT PAPER NUMBER

1617

DATE MAILED:

04/24/01 4

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/703,753	DUDLEY, ROBERT E
	Examiner	Art Unit
	Shaojia A. Jiang	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-56 is/are pending in the application.  
 4a) Of the above claim(s) 1-31 and 51-56 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 32-50 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claims 1-56 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15) Notice of References Cited (PTO-892)                    18) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.  
 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    19) Notice of Informal Patent Application (PTO-152)  
 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ .                    20) Other:

### **DETAILED ACTION**

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Since applicant has two set of originally presented claims numbered 34 and 35, beginning with the second set of claims numbered 34 and 35, the claims herein have been renumbered in accordance with Rule 126, and the dependency of renumbered dependent claims has been completely changed as well. Thus, the claims herein are now numbered 1-56 instead of 1-54.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16 drawn to a method of improving sexual performance in a male, classified in class 514, subclass 178.
- II. Claims 17-31 drawn to a method of increasing the libido of men, classified in class 514, subclass 178.
- III. Claims 32-50 drawn to a method for improving the efficacy of a pharmaceutical useful for treating erectile dysfunction in a male, classified in class 514, subclass 178.

IV. Claims 51-56 drawn to a pharmaceutical kit comprising specified components herein, classified in class 514, subclass 178.

Inventions Group I-III; and Group IV are related as process of use and product.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case an alpha-adrenergic receptor antagonist may be useful in a method of improving sexual performance in a male.

Groups I, II, and III are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are separate and distinct each from the other because they have different functions.

The invention of Group I functions to improve sexual performance in a male. The invention of Group II functions to increase the libido of men. The invention of Group III functions to improve the efficacy of a pharmaceutical useful for treating erectile dysfunction in a male. Therefore, Groups I, II, and III have different functions.

The search for all inventions would place an undue burden on the Office in view of the corresponding diversity in the field of search for each.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Joseph A. Mahoney on March 16, 2001 a provisional election was made with traverse to prosecute the invention of Group III, claims 32-50. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-31 and 51-56 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objection***

Claim 49 is objected to for minor informalities. The expression "effective amount steroid" in the claim is considered informal. Appropriate correction is required. The expression, "effective amount of a steroid" in the claim would be favorably considered.

Claim 50 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is well settled that

recitation of an inherent property of a composition or method will not further limit claims drawn to a composition or method.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-36, 38-39, 41-46, 48, and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "derivatives" in claim 35 renders claim 35 indefinite. The expression " derivatives " is not defined by the claims. Therefore, the scope of claims is indefinite as to derivatives encompassed thereby. *OK*

Claim 38 recites the limitation "the fatty acid" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 39 recites the limitation "the lower alcohol" in the claim. There is insufficient antecedent basis for this limitation in the claim. *OK*

Claims 43-44 recite the limitation "the thickerner" in the claim. There is insufficient antecedent basis for this limitation in the claim. *NO*

Claims 45-46 and 50 recite the limitation "the men" in the claim. There is insufficient antecedent basis for this limitation in the claim. *OK*

Claim 48 recites the limitation "the right/left upper arms/shoulds" in the claim. There is insufficient antecedent basis for this limitation in the claim.

The expressions "1.0 g w/w of " and "0.5 g w/w of " in claims 41-42 render claim 41-42 indefinite. The expressions "1.0 g w/w of " and "0.5 g w/w of " are not understood in terms of absolute weight or percentage of weight.

Claims 36 and 43-44 contains the trademark/trade name VIAGRA, UPRIMA, *TC*, TRENTEL, ACTIBINE, and CARBOPOL. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe particular pharmaceuticals herein and, accordingly, the identification/description is indefinite.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omar (5,730,987, A, PTO-892) and Mak et al. (N, PTO-892) and Moreland et al. (U, PTO-892) in view of Allen (O, PTO-892).

Omar discloses that the particular steroid, testosterone and yohimbine HCl (ACTIBINE) or a combination thereof to be administered are useful in the composition and the method of the treatment of impotent in human males, i.e., erectile dysfunction. See col.1 lines 17-62 and claims 6-8.

Mak et al. discloses an enhancement of the penetration of transdermally (percutaneously) or topically applied a pharmaceutical composition comprising an active agent, testosterone, and a penetration-enhancing system that comprises oleic acid (a fatty acid having 17 carbon atoms), C1-C4 alcohol (e.g., ethanol, 2-propanol), and the gelling agent (a thickener), CARBOPOL (a polyacrylic acid). See abstract, page 3 lines 1-5, page 10 Example 1, and Figure 2.

Moreland et al. teaches that the phosphodiesterase type 5 inhibitor, sildenafil, is useful in the treatment of male erectile dysfunction. See Abstract and Introduction.

The prior art does not expressly disclose a method for improving the efficacy of a pharmaceutical useful for treating erectile dysfunction in a male who may be an eugonadal comprising the particular steroid, testosterone, C1-C4 alcohol, and the particular penetration enhancer, isopropyl myristate, and the effective amounts of active ingredients in the composition.

Allen discloses a topical cream composition useful for treating male erectile dysfunction comprising the particular penetration enhancer, isopropyl myristate. See abstract and claim 1 and 4.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular steroid, testosterone, C1-C4 alcohol, and the particular penetration enhancer, C8-C22 fatty acid and isopropyl myristate in a method for improving the efficacy of the composition herein useful for treating erectile dysfunction in a male who may be an eugonadal, and to further add the phosphodiesterase type 5 inhibitor, sildenafil or yohimbine HCl to the composition, and optimize the effective amounts of active ingredients in the composition.

One having ordinary skill in the art would have been motivated to employ the particular steroid, testosterone, C1-C4 alcohol, and the particular penetration enhancer, C8-C22 fatty acid and isopropyl myristate in a method for improving the efficacy of the composition herein useful for treating erectile dysfunction in an eugonadal male since the particular steroid, testosterone, is well known to be useful to treat erectile dysfunction in a male according to Omar. It is also well known that an eugonadal male suffers erectile dysfunction. Moreover, the composition containing testosterone of Mak et al. is known to be useful in a method for improving the efficacy of percutaneously delivering a pharmaceutical because this composition further comprises a transdermally or topically penetration-enhancing system encompassing an oleic acid (a fatty acid having 17 carbon atoms), C1-C4 alcohol (e.g., ethanol, 2-propanol), and the enhancer, CARBOPOL. Therefore, one of ordinary skill in the art would have found it obvious to

employ the composition of Mak et al. in the instant claimed method. The topical cream composition of Allen is also known to be useful for treating male erectile dysfunction comprising the particular penetration enhancer herein, isopropyl myristate, which provides additional motivation for the claimed method. One of ordinary skill in the art would also have been motivated to add the phosphodiesterase type 5 inhibitor, sildenafil or yohimbine HCl to the composition since the combination of testosterone and yohimbine HCl or yohimbine HCl alone or sildenafil are all known to be useful in the treatment of male erectile dysfunction according to Omar and Moreland. Therefore, one of ordinary skill in the art would have reasonably expected that adding yohimbine HCl or sildenafil to Mak's composition would improve the therapeutic effect of Mak's composition to treat male erectile dysfunction. Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of amounts of active agents to be administered is considered well within the skill of artisan.

Since all composition components herein are known to be useful to treat male erectile dysfunction, it is considered *prima facie* obvious to combine them into a single composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
April 13, 2001

*Minna Moezie*  
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